# Healthcare Information Standards & Testing: A Concept Paper

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August 13, 2002

**Preface**

This paper was inspired by preliminary discussions between NIST and members of the healthcare community who are impacted by the use of emerging information technology. Topics of discussion included the current state of standards work in the healthcare community, the requirements for security, information assurance and continuity-of-operations, as well as the critical need for information interoperability to provide healthcare information and clinical care. Participants of the recently held NIST Workshop, *Information Technologies for Healthcare: Barriers to Implementation,* reiterated these same topics. Throughout a major theme has emerged – the plethora of healthcare standards and the need for conformance tests and testing programs. This initial paper focuses on options for analyzing, defining, and organizing appropriate standards for the healthcare community and the issues surrounding conformance testing. Further studies and discussions may uncover more information regarding other issues and challenges facing the healthcare industry and its segments, including, but not limited to, security, user interfaces, information retrieval, pervasive computing technologies and networking. These issues could then foster opportunities that allow NIST to work collaboratively with the healthcare industry to address the challenges that arise.

## Challenges for Healthcare Standards and Testing

The demand for online medical information and simplified, standardized methods to access healthcare information and services is crucial in making healthcare safe and available to all. At the same time, the public as well as the healthcare provider must have confidence that their online communications are secure and their privacy protected, and that the digital representation and exchange of information is accurate and correct. Moreover, it is critical that security and continuity of operations is assured. Appropriate standards for healthcare information and systems provide the cornerstone to achieving a 'healthy' healthcare infrastructure.

Standards are vital to health care systems and the deployment of information technologies for healthcare. This has led to a flurry of standards development and deployment activities by numerous accredited standards developing organizations (SDOs), consortia, trade associations, government agencies, and individual companies. The range of healthcare standards run a wide gamut and span several tiers of the healthcare industry.

There is a real need for coordination of these efforts to leverage the synergy of the various efforts, to harmonize vocabularies, to enable interoperability, and to promote consistent testing and certification programs across and within organizations. Consistent testing and certification programs lead to interoperability of information and implementations as well as mutual recognition of tested products. The conformance testing and validation principles described in this paper allow for varying degrees of formality in the formulation of the validation programs. The most informal of programs occurs when implementers self-test with publicly available test suites- a common approach in today's internet-time environment. The most formal validation program requires independent, third-party testing by nationally accredited testing laboratories. These are more appropriate when dictated by regulation. Other testing and validation strategies lie somewhere in the middle between these two extremes.

The objective here is to stimulate discussion on how the foregoing concepts can be mapped to specific healthcare industry requirements and, thus, to explore possibilities for collaboration between the healthcare community and NIST

## A Standards Roadmap: Making Order Out of Chaos

The healthcare industry is not unique in having a plethora of standards that are developed by multiple organizations. Nor is it unique in trying to track the various standardization activities while attempting to connect those who seek standards with those who supply them. Other organizations, such as ANSI, OASIS (the Organization for the Advancement of Structured Information Standards) and the OMG (the Object Management Group) are facing the same situation and challenges with respect to electronic business specifications. However, healthcare is unique with its diversity of standards – infrastructure standards; clinical information standards; business information standards, as well as standards within each medical discipline. The users of these standards cover the full spectrum of healthcare participants, from consumer to provider to HMO to pharmacist to insurer, where each group has different but related sets of requirements with respect to the standards.

Healthcare standards may be numerous, but they are not necessarily compatible. Compatibility is very important in using standard components to construct a truly useful, larger (infra) structure of healthcare service. Any effort to extract information about the standards, as well as to develop profiles (i.e., a stack of standards) and conformance testing methodologies, needs to be examined closely to ensure that broad coverage exists to serve the needs of the whole community, not just one special sector.

A prerequisite to determining the type of testing and validation program that would be applicable to ATA and its members (or any organization) is knowledge of the standards landscape. This includes but is not limited to: identification of all applicable standards; assessment of the maturity or status or utility of each standard; integration and compatibility of each standard with other standards; business models and use cases from which the standards are derived; and the business model that supports testing efforts. Currently this information is not easily obtained by canvassing a few significant

healthcare organizations or the Web in general. For example, web searches give some information but in general do not provide complete pictures. This may be due to several reasons, including the lack of common vocabulary - everyone describes their work differently. An in-depth look at one or more organization's websites may produce the desired information but may take precious time in finding and reading through multiple web pages and documents.

One way to capture the knowledge of standards within a community-of-interest such as healthcare is to establish a 'standards roadmap' of existing and emerging standards. The goal of a roadmap is to provide a recognized, easy to use, and unbiased source of standards information that provides a comprehensive and comparative view of current and emerging standards. The roadmap should be interactive, providing the user with related/compatible standards if a given standard is chosen. Information contained in the roadmap should include descriptions of the standards, type of use, maturity level, relation to other standards, etc. Additionally the roadmap is used to target those standards for which conformance tests are necessary (or advocated) as well as where tests and testing services are available. The roadmap acts as an interface into a registry of metadata information about standards.

By using XML technologies as the basis of the roadmap, it is scalable and extensible to accommodate the ever-changing standards landscape and is adaptable to the various stakeholders' requirements. The benefits of an interactive roadmap are manifested by its ability to:

- Improve the efficiency of and reduce costs in developing standards;
- Achieve greater coordination and collaboration across and within organizations;
- Enhance public participation in standards development and access to standards.

Specifically, a standards roadmap helps users identify and locate the standards they need while helping them understand the interrelationships between various standards documents available or under development. The information is conveniently located within a single source, eliminating the need for multiple searches through different information sources. Additionally, users may have exposure to standards and activities which were previously unknown to them. For standards organizations, having their standards included in the roadmap – a highly visible service – can help publicize their standards to the healthcare community. Ultimately, this leads to better communication between the various organizations, resulting in less overlap of efforts and interoperability of completed work.

**Standards Roadmap: Where to begin**

In carrying out the activities needed to build and establish a standards roadmap, it is necessary to be familiar with the variety of relevant healthcare standards activities. Initial steps include:

- establish a community-of-interest;

- organize the effort;
- identify existing work or similar efforts;
- define use cases; and
- develop a metadata and taxonomy.

Use cases help to identify and clarify the functional requirements of the roadmap. Use cases capture all the different ways the roadmap would be used, including the set of interactions between the user and the roadmap as well as the services, tasks, and functions the roadmap is required to perform.

Care should be taken in defining the metadata and taxonomy to ensure that it appropriately describes the standards activities. Additionally, it is critical that participants in this effort endorse the metadata and taxonomy. This ensures not only their support but also their participation in registering their standards activities in the Standards Roadmap.

The basic building blocks of a Standards Roadmap include:

- a defined set of descriptive metadata;
- taxonomies that are used for categorizations;
- a user interface that is understandable by the community-of-interest; and
- a registry that stores the data.

The use of XML technologies provides a flexible method for defining the necessary metadata that can easily be processed by a variety of applications. In particular, an XML schema provides the standardized description of each standard though a set of tags, structure, and constraints. A forms-based user interface allows users to make queries, based on categorizations, against the standards listed and ultimately generate a report that meets their specific needs and interests.

An example of a standards roadmap is a prototype that NIST developed for the General Services Administration for electronic commerce (EC) standards and activities. The objective of the *GSA Roadmap* (http://www.nist.gov/roadmap) is to provide GSA, Federal agencies and vendors a comprehensive and comparative view of emerging EC standards. The roadmap is an interactive web application with functionality that provides the user with the ability to access predefined reports or customize a report, assist in populating the database by submitting information related to a standard, and look at the technology used to create the roadmap (via a tutorial). Note that the *GSA Roadmap* is a work in progress and as yet, is not fully operational, nor does it contain complete standards information.

## Conformity Assessment: Industry's Motivation

In the marketplace, conformity assessment provides a vehicle for exchanging information between a buyer and a seller. It increases a buyer's (or user's) confidence in a product and its ability to meet their needs. For sellers (and implementers), conformity assessment can help to substantiate claims that a product meets a given specification.

Often conformity assessment is accomplished by conformance testing. Conformance testing is a means of measuring whether a product faithfully implements a specification. The level and formality of the testing are determined by the market – the requirements of the buyer directly or an organization acting on behalf of a community of buyers, or by regulation (e.g., safety, health, or national security concerns). For example some programs may require a very formal testing and validation approach consisting of independent (i.e., third party), nationally accredited testing laboratories, while others may be more appropriate for self-declaration and demonstration testing.

Any industry group, consortia or standards body, in determining whether to address conformity assessment, should go through a process of fundamental cost/benefit analyses. What are the benefits to users of testing implementations to a particular specification (or set of specifications)? (Is there a real need?) What are the benefits to implementers (of the specifications) in having tests available? What are the risks to an organization of using potentially non-conformant products? What level of assurance does an organization require that its products conform to a particular specification? What is the cost of implementing and maintaining a conformity assessment program to the organization? And finally and most importantly, what is the cost to the implementers in having to use the conformity assessment program? Obviously, if implementers (i.e., those who implement the specifications) cannot create or modify business models that can factor in the additional cost of testing, then the program is doomed to failure. Each of these questions must be explored in detail, and the answers should not be trivially derived.

### Conformance Testing and Validation: The Definition

Conformance testing is a method of verifying implementations of a specification to determine whether or not deviations from the applicable specification exist. It applies to the testing of software for which there are de jure or de facto standards, such as network protocols, message formats, markup languages, imaging techniques, and security. Conformance testing is a way to increase the likelihood that software products claiming to adhere to a specification are implemented correctly. Correct implementation and utilization of standards leads to interoperability – the capability of two or more systems to exchange and make use of data.

To test that a specification is faithfully adhered to, one must scrutinize the specifications and methodically compare the implementation's results against the syntax (the structure)

and semantics (the intent) contained in the specification. Conformance testing encourages implementers to pay more attention to the standard and to produce a higher quality implementation to "pass" the conformance testing process.

The intent of conformance tests is twofold: 1) to be used by implementers early on in development to improve the quality of their implementations; and 2) to be used by industry associations wishing to administer a testing or validation service. NIST focuses on the technical task of developing test suites (with the private sector), leaving the regulatory aspects of testing and validation to the private sector (with the exception of IT security testing). However NIST provides guidance and expertise to industry associations interested in making use of the conformance test suites and establishing testing and validation programs.

Validation is the act of asserting 'conformance' of an implementation to a standard. In a formal validation program, a standards body or consortia issues a certificate to the organization whose implementation was tested. The certificate typically denotes that the organization has correctly implemented the standard in its product, but may sometimes (e.g., for legal liability reasons) simply denote that the appropriate testing procedures appear to have been followed.

**Conformance Testing and Validation: The Process**

Conformance Testing and Validation encompasses three major processes: conformance test development, conformance test use, and validation. Each of the three processes can be designed using a number of different models; most of which NIST has helped industry implement.

*Conformance Test Development:* Developing conformance tests (a conformance test suite) is an elaborate, highly technical, and complex process involving the scrutiny of very sophisticated and often large specifications and the generations of large amounts of test data. Additional challenges are incurred when the goal of the testing effort is to verify conformance to a stack of standards integrated into a given system. (Semantics of integration are usually not addressed in a standard.) Recent efforts in NIST have focused on improving the test development process through automated techniques. NIST partners with industry in developing tests. Many implementers have their own set of conformance tests (for product development) and are often willing to contribute them for the benefit of the industry. Participation by implementers not only allows for the development of a more comprehensive test suite, but also has the ultimate benefit of achieving industry buy in to the process as a whole. Of course, this process must be moderated by a neutral third party (such as NIST) to ensure high quality of the industry contributions as well as a lack of bias toward their own products.

Testing procedures define the administrative as well as technical process for testing an implementation. This includes the documentation of how testing is to be done and the directions for the tester to follow. Good testing procedures are detailed enough to allow for test results to be repeatable by the same tester and reproducible by a different tester.

An adequate testing procedure provides test results that give enough information so that conformance can be measured. An appropriate test method is one that, while adequate, does not place undue requirements on the implementer and is cost justifiable. If the testing procedure is too expensive to employ, then it will not be used. The definition of adequate and appropriate is left to the validating organization to define.

*Conformance Test Use:* The use of the conformance test suite and its accompanying testing procedures is directly related to the formality of the conformity or validation program. The most formal of programs requires an implementer to contract with an accredited, independent third-party testing laboratory to have conformance testing performed. The implementer and the laboratory negotiate the scope of testing, the cost of testing and the timeliness of testing. The test results are then made known to the organization issuing the validation certificate. (Obviously this is the most costly of models for the implementer.) The least formal constitutes an implementing organization performing the tests itself (self-test) and publicly reporting the results.

*Validation:* Upon completion of testing, the results are documented in a conformance test report. The test report also contains information about the implementer (the organization), the test environment, the test suite version and any other appropriate information required during the testing process. If the implementation that was tested has successfully completed all tests and meets the validation criteria, the validation organization issues a Certificate of Validation. Typically a public register is maintained containing a listing of products that have received Certificates of Validation.

**Conformance Testing and Validation: Degrees of Formality and Adaptation**

Generally, validation is performed for critical applications to assess security, or to achieve interoperability with other applications. The level and formality of the testing and validation effort is determined by the buyer, an organization acting on behalf of a community of buyers, or regulation (e.g., safety, health or national security). Typically, the decision to establish a validation program is based on weighing the benefits achieved by obtaining conformance versus the cost of creating and maintaining a validation program versus the ultimate cost impact to implementers and thus the industry.

Traditionally, validation programs have been very formal and sponsored by organizations such as a government agency or trade association and culminating in the award of a validation certificate. Validation programs have also been used as a prerequisite for procurement. More recently with the advent of the Internet, the web, and rapidly changing information technology, the notion of validation has been expanded. It has become less formal, allowing implementers and users to assess for themselves, the validity or correctness of the software or data with respect to a relevant specification. They can make any necessary corrections to allow the implementation to conform. This Self-Serve Validation makes use of publicly available test suites or tools and is not associated with any formal validation program.

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The most common examples of Self-Serve Validation is checking the syntax of a program or message by submitting it to a syntax checker, validating parser or test implementation.  For example, the World Wide Web Consortium (W3C) provides validation services via on-line validators for Hypertext Markup Language (HTML) and Cascading Style Sheets (CSS).  This is a Self-Serve Validation Service.  Users access these tools via a URL and conduct their own testing.  There are no formal procedures, no certificates issued, and no list of validated products maintained.  Additionally the W3C makes all of their conformance test suites publicly available for implementers to use to ensure correctness.  As with the on-line validators, this is a Self-Serve Validation Service.

An example of a formal validation program is the Cryptographic Module Validation Program (CMVP).  The CMVP was established to provide independent testing and validation to NIST's *Security Requirements for Cryptographic Modules, Federal Information Processing Standard 140-1 (FIPS 140-1)*. The current version is FIPS 140-2.  The requirement for validation is specified in the FIPS 140-2 standard.  Therefore, this program is based on a regulatory requirement.  NIST and the Communications Security Establishment of the government of Canada serve as the issuer of certificates of validation for the federal governments of both countries.  As such, the certificates are considered to be second-party (i.e., NIST and CSE are acting on behalf of the users of FIPS 140-2).  Testing laboratories must be used to perform the testing process and are required to be accredited by NIST's National Voluntary Laboratory Accreditation Program.  The CMVP requires that testing laboratories be independent from implementers (i.e., third-party testing).

## NIST Competencies and Potential Roles

NIST works with industry, research, and government organizations to make emerging information technology more usable, more secure, more scalable, and more interoperable than it is today. Through NIST developed tests, test methods, measurements and related material, both the implementers and the users of information technology can objectively measure, compare and improve their systems.  Additionally NIST, through its standards expertise, assists the IT industry and appropriate vertical industries with their standards development efforts; helping to ensure that standards are complete, unambiguous and testable.  The following highlights some of our core competencies that may be applicable to the healthcare industry's IT needs:

- Standards Development (with industry) and Standards Integration;
- Conformance Test Development;
- Validation Program Guidance;
- Security Technologies;
- XML Technologies;
- Integration of Information;
- Retrieval and Rendering of Information; and
- Pervasive Computing Technologies and Networking
- Simulation of Work Flow Processes.

Applying NIST strengths to the initially perceived requirements of the healthcare industry (actually to particular segments) the following picture emerges with respect to potential NIST contributions:

- Healthcare Standards Roadmap Development;
- Healthcare Standards Gap Analysis;
- Conformance Test Development of Appropriate Healthcare Standards;
- Validation Program Guidance for Relevant Healthcare Standards Bodies and Consortia;
- Guidance on Appropriate Use of IT Security Technologies;
- Guidance on Developing Appropriate User Interfaces, Including Speech Recognition
- Information Modeling Integration of Healthcare Information Models; and
- Neutral Facilitator for Building Bridges between Healthcare Standards Bodies and Consortia;
- Analysis and Modeling of Healthcare documents workflow process.

Please note that the list above is based on a minimal amount of information collected to date regarding specific healthcare industry needs. Further studies will uncover more information regarding the specific challenges facing the healthcare industry and its segments. These challenges could then foster collaborative opportunities that allow NIST to be most effective for the healthcare industry.